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Duncan Smith, T.D.
Dáil Éireann,
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23rd December 2022

PQ: 61498/22

To ask the Minister for Health the average time taken by the HSE to decide on applications for medications to be added to the reimbursement list; the average time taken to adjudicate on hardship cases where manufacturers are seeking price increases due to inflationary costs; and if he will make a statement on the matter. -Duncan Smith

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 61498/22), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement, in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(1) The health needs of the public,
(2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(3) The availability and suitability of items for supply or reimbursement,

(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and,
(9) The resources available to the HSE.

The HSE is required to consider the following criteria when it is making decisions in relation to pricing of Medicines:
(*a*) the equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,
(*b*) the relevant prices of therapeutically similar listed items,
(*c*) the potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,
(*d*) the potential budget impact of the item if it were to become a listed item,
(*e*) the ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,
(*f*) the resources available to the Executive, and
(*g*) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item

In 2020 and 2021 the HSE approved approximately half of all applications for pricing and reimbursement within 60 days of receipt of the application. This includes applications for generic medicines, biosimilar medicines, hybrid medicines and new chemical entities (orphan and non-orphan) and excludes applications for parallel imported medicines.

In December 2021 the State agreed two multiannual agreements with the Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI):

- Framework Agreement on the Supply and Pricing of Medicines (i.e., the 2021 IPHA Agreement)
- Framework Agreement on the Supply and Pricing of Generic, Biosimilar, and Hybrid medicines (i.e., the 2021 MFI Agreement)

These framework agreements on the supply and pricing of medicines contribute to the sustainable funding of new and existing medicines and are estimated to deliver additional savings to the State. The savings achieved are via a number of measures outlined in the agreements including enhanced price reductions for off-patent medicines and increased rebate contributions for on-patent medicines.

In the interests of continuity of supply, where it becomes uneconomic for a Supplier to supply a particular medicine under the terms of the Agreements, direct representations may be made by the Supplier to the HSE for variation of any term of the Agreement, in relation to that medicine, including its price terms (Section 14.4 of the 2021 IPHA Agreement and Section 13.4 of the MFI Agreement outlines exceptional circumstances processes for the

respective Industry members). Where representations are made to the HSE under this Clause, the HSE shall have the final decision on whether to vary the terms of the Agreement

in any case but will consult with the Supplier before reaching its decision. The HSE expects a robust submission of evidence to support any claim, from any Supplier, in the event that they wish to set out to the Executive an inability to meet pricing terms set out in said Agreements.

In 2022 the HSE has approved several pricing increase requests, including to address the well-publicised case of paracetamol shortages arising in 2022, to cover an unexpected and sudden increased cost of goods arising from the manufacture of this commonly prescribed and essential medicine. As of December 2022 there are 5 applications from 4 separate manufacturers/suppliers currently under review by the HSE, for a pricing increase request related to a claim of increased cost of goods making continuity of supply to the Irish market and Irish patients unsustainable. In the case of such pricing increase requests the time taken to adjudicate on these is highly variable (on a case by case basis) and dependent on a number of factors, that the HSE is required to consider. These include but are not limited to the number of alternative suppliers for that medicine, the potential alternative therapeutic options, the clinical need for the product, the potential budget impact, European pricing as well as other applicable matters, for example whether there are pending cases being brought before relevant competition authorities where companies are under active investigation for unfair and disproportionate pricing hikes for their medicines (that can arise in particular where there are single source suppliers i.e. monopoly positions). The HSE also takes an active role at the time of notification, in engaging with manufacturers/suppliers intending to discontinue priority medicines due to the lack of commercial viability of those products. In many of the cases where this arises as a scenario, the commercial decision relates to global discontinuations and is outside of the control of the HSE i.e. cannot be addressed through pricing increases at a national level.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service